



Drug Utilisation and Health Policy (DUPHO) meeting

November 30 - December 3, 2011, Antwerp, Belgium

**An initiative of ISPE's Drug Utilization Special Interest Group –
European Branch - EuroDURG**

**A Report Prepared for the ISPE Board Meeting – Miami –
21st April 2012**

Contents:

Page 2 – Executive Summary
Page 4 – Full Report
Page 39 - Financial Outcome

EXECUTIVE SUMMARY

The DUPHO meeting took place at the beautiful campus of the University of Antwerp and provided unforgettable days for DU researchers in all aspect. It was a joint educational course and scientific meeting organized by EuroDURG in close collaboration with ISPE. The meeting was sponsored by ISPE, Associazione DURG Italia, Cegedim Strategic Data, RIZIV-INAMI Belgium, University of Antwerp, University Medical Center Groningen, University of Ghent (Heymans Institute), University of Stockholm (Karolinska Institute), WHO Drug Statistics Centre and WHO Centre of Pharmacoepidemiology of the University of Utrecht.

The meeting aimed:

- to offer public servants and researchers basic and advanced statistical and pharmaco-epidemiological methods for handling drug utilisation data
- to discuss advantages and limitations of drug utilisation data derived from different sources like medical records and reimbursement databases
- to deepen the knowledge of drug utilisation and pharmacoepidemiological research to support health policy interventions and the quality of prescribing

The DUPHO meeting started with educational sessions handling DUR units of analysis, quality indicators, the impact of interventions and biostatistics for drug utilisation research. Key lectures focused on drug utilisation research as a tool for health policy and innovation management, on comparative effectiveness research and implementation strategies to enhance the quality and efficiency of future prescribing. Additionally, workshops and interactive sessions were organized on cross-national comparison and the validity of data sources, the role of drug utilisation data in pharmacovigilance and epidemiological measures in patient identity databases.

The local organizers welcomed a total of 145 attendees from 28 countries and five continents. The call for abstracts resulted in 122 submitted abstracts with 59 of them being new abstracts. Sixteen were selected for oral presentation. The remaining were presented during the CNC poster walk on Thursday and the special poster walk session on Friday, where all authors had the opportunity to present their work.

Attendees of the meeting were offered an attractive social program with a welcome drink and a guided tour at the University on Wednesday, a dinner at the university club on Thursday and a EuroDURG party on Friday.

Shortly after the end of the DUPHO meeting a web questionnaire was sent out to all conference participants including speakers and members of the scientific committee. All respondents were asked about their previous participation of DURG/ISPE conferences and to rate the scientific content and relevance as well as the social program and the practical arrangements. Furthermore, they were asked to rate all the different sessions and to give individual comments and suggestions for future meetings. All ratings were done on a ten-grade scale with 10 being most positive.

A total of 104 (72%) responded to the questionnaire with academia being the most common affiliation with 52% of all participants. Around half of all participants (49%) had participated in a previous meeting held by ISPE and/or EuroDURG. The mean rating of the value of the conference was between 8 and 9 for all general aspects of the conference (scientific content, relevance for work, social program, establishing contact/networking, practical arrangements). All topics of the conference were appreciated with mean ratings between 7-10. A lot of ideas of topics for future conferences were suggested. Some examples are electronic decision support systems, risk benefit evaluation of medicines by patients, different data sources for drug utilisation research and their strength and limitations, drug use in hospitals, how to plan a study, drug use in children and the elderly, methodologies for changing prescriber behaviour, determinants/models/theories of suboptimal prescribing behaviour.

Some citations added as 'free comment' to the questionnaires:

"A very well organized conference with fantastic speakers. I really enjoyed it. When is the next conference?"

"In comparison with the annual ISPE meetings, this meeting was positively very intensive for my research interest"

„in short, excellent"

"Thanks for the terrific effort put into this meeting as well as the excellent scientific content"

"Extremely well organized. Very educational"

"Great to have a real DU-meeting again! Good mix of participants (academia-health policy-healthcare)"

Conference report

***The Scientific Committee of
the ISPE/EuroDurg meeting
in Antwerp 2011****

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The report from the scientific program was written by the committee above with substantial contributions also from Thomas Cars, Maria Ingemansson, Maria Juhasz-Haverinen, Linnea Karlsson, Desirée Loikas, Jelina Nordin, Miriam Qvarnström and Katarina Schmidt-Mende, all from Karolinska Institutet and Stockholm County Council in Stockholm, Sweden.

Preface

This report summarizes the proceedings of the Drug Utilisation and Health Policy meeting (DUHPO) organized by ISPE/EuroDurg in Nov-Dec 2011 in Antwerp, Belgium. The conference was the first large meeting in many years specifically targeted at drug utilization research. A total of 150 attendees from 28 countries signed up including 110 registered participants, 40 speakers and members of the scientific committee. A total of 122 abstracts were submitted with 59 of them being new abstracts that hadn't been presented on a previous conference. The meeting was well received by all participants as presented in this report.

In this report, we aim to give an overview of the scientific content, the submitted studies, the cross national comparative sessions and the overall evaluation of the meeting. The texts are written by different members of the scientific committee substantial contributions also from Thomas Cars, Maria Ingemansson, Maria Juhasz-Haverinen, Linnea Karlsson, Desirée Loikas, Jelina Nordin, Miriam Qvarnström and Katarina Schmidt-Mende, all from Karolinska Institutet and Stockholm County Council in Stockholm, Sweden. We also wish to adress our special thanks to Dr Pia Bastholm-Rahmner and Dr Aniko Veg at Stockholm County Council for help with the online evaluation of the meeting and to Yoleen Van Camp for enthousiastic administrative support before, during and after the conference.

Stockholm and Antwerp, April 2012

Björn Wettermark, PhD
Chair of the scientific committee

Monique Elseviers, professor
local meeting organizer

Table of Contents

Preface

1. General summary of the meeting
2. Educational sessions
3. The scientific program
 - 3.1 Key note lecture – “Better public health through pharmacoepidemiology and quality use of medicine”
 - 3.2 Cross national comparisons of drug utilization
 - 3.3 Innovation management and drug utilization
 - 3.4 Adherence in drug utilization research
 - 3.5 Validation studies of data and indicators
 - 3.6 Drug utilization research in benefit-risk evaluation
 - 3.7 Epidemiological measures of DU in patient identity databases
 - 3.8 Generics in Drug Utilization research
 - 3.9 Interventions to improve Drug Utilization
 - 3.10 The future of quality use of medicine:
From measurements to implementation
4. Literature Review on cross-national comparison of DU activities
5. Submitted abstracts
6. Awards
7. Evaluation of the meeting

1. General summary

The DUHPO meeting was a joint educational course and scientific meeting organized by EuroDURG in close collaboration with the International Society of Pharmacoepidemiology and Drug Safety (ISPE). The meeting was sponsored by Associazione DURG Italia, Cegedim Strategic Data, ISPE, RIZIV-INAMI Belgium, University of Antwerp, University Medical Center Groningen, Heymans Institute of the University of Ghent, Karolinska Institutet, WHO Drug Statistics Centre and WHO Centre of Pharmacoepidemiology of the University of Utrecht.

The meeting aimed:

- ❖ to offer public servants and researchers basic and advanced statistical and pharmacoepidemiological methods for handling drug utilization data
- ❖ to discuss advantages and limitations of drug utilization data derived from different sources like medical records and reimbursement databases
- ❖ to deepen the knowledge of drug utilization and pharmacoepidemiological research to support health policy interventions and the quality of prescribing

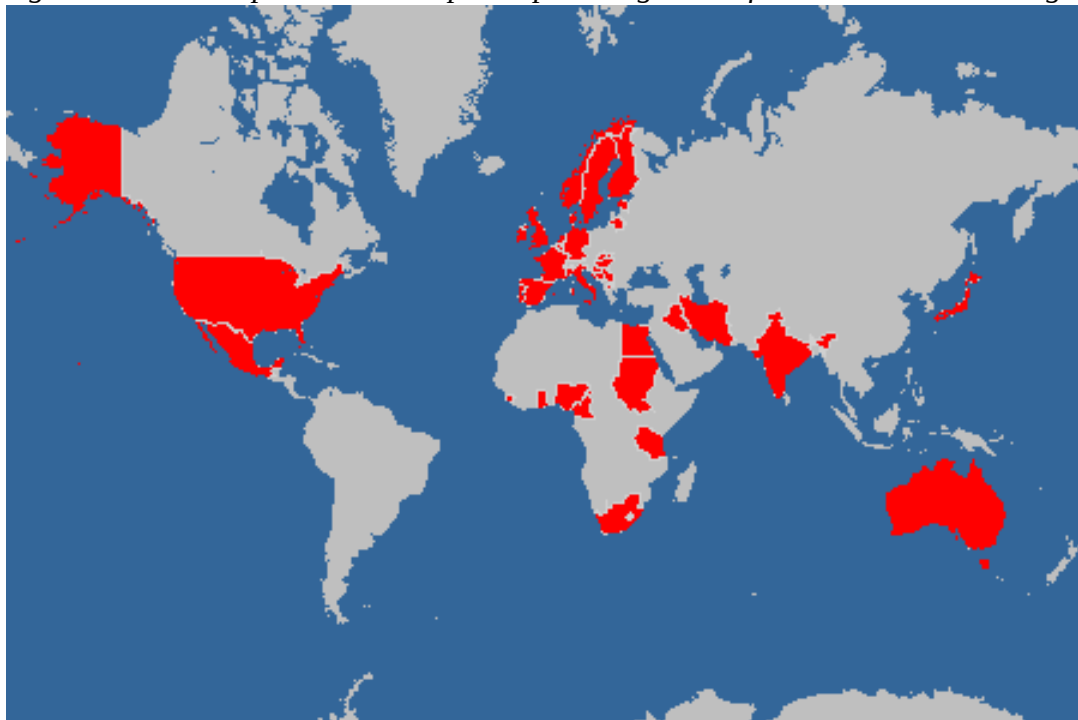
The conference started with educational sessions handling units of analysis, quality indicators, the impact of interventions and biostatistics for drug utilization research. Key lectures focussed on drug utilization research as a tool for health policy and innovation management, on comparative effectiveness research and implementation strategies to enhance the quality and efficiency of future prescribing. Additionally, workshops and interactive sessions were organized on cross-national comparison and the validity of data sources, the role of drug utilization data in pharmacovigilance and epidemiological measures in patient identity databases. The full program is presented in the appendix.

The meeting venue was the Hof Van Liere, the conference centre of the University of Antwerp, located in the historical centre of Antwerp.



The local organizers welcomed a total of 150 attendees from 28 countries including 110 registered participants, 40 speakers and members of the scientific committee.

Figure. Countries represented with participants registered for the DUHPO meeting.



The call for abstracts resulted in 122 submitted abstracts with 59 of them being new abstracts. Sixteen were selected for oral presentation. The remaining were presented during the CNC

poster walk on Thursday and the special poster walk session on Friday, where all authors were offered the opportunity to present their work. Among the abstract submissions, the best oral presentation and the best poster presentation were selected and awarded with a reimbursement of their registration fee (see DUHPO awards below).

Attendees of the meeting were also offered an attractive social program with a welcome drink and a guided tour on Wednesday, a dinner at the university club on Thursday and a EuroDURG party on Friday. Pictures of all events are available at the meeting website www.ua.ac.be/eurodurgmeeting

2. Educational sessions

The DUHPO meeting began with seven hours of educational sessions on different topics related to drug utilization research. The educational sessions started with an overview of pharmacoepidemiology and drug utilization research and the expected outcome from the different course sessions. Lectures were held by professor Robert Vander Stichele, professor Monique Elseviers and Dr Björn Wettermark on definitions, methodological framework, skills needed and why drug utilization research is an important tool in health policy. The definition of drug utilisation, used as a framework both for the educational sessions and the scientific program, was that drug utilization is "An eclectic collection of descriptive and analytical methods for the quantification, the understanding and the evaluation of the processes of prescribing, dispensing and consumption of medicines, and for the testing of interventions to enhance the quality of these processes."¹. By using the definition all studies could be classified in either descriptive, analytical or interventional drug utilization studies focusing on the different aspects of the prescribing process from physician prescribing or pharmacy dispensing and actual consumption of medicines as measured at the patient level through various methods. Adopting the definition above, drug utilization research also incorporates qualitative studies on the perceptions of prescribers, patients and other stakeholders in dealing with medicines.

Subsequent educational sessions were targeted at classification systems, measurement units of utilization and expenditure, feedback on prescribing patterns, quality indicators, biostatistical methods and impact of interventions.

¹ ¹Björn Wettermark, Vera Vlahovic -Palcevski, Hege Salvesen Blix, Marit Rønning, Robert H Vander Stichele. Drug Utilisation Research. Pharmacoepidemiology: An Introduction. Second Edition. Edited by A. Hartzema, M. S. Porta, and H. H. Tilson. Harvey Whitney Books. ISBN 0-929375-03-3.

The session on *classification systems and measurement units of utilization* was organized by Hanne Strøm, Hege Salvesen Blix and Solveig Sakshaug from the WHO collaborating Centre for Drug Statistics Methodology in Norway. They gave an overview of different classification systems and measurement units with special emphasize on the Anatomical Therapeutic Chemical (ATC) classification system and the concept of Defined Daily Doses (DDD). The benefits and limitations regarding the use of ATC and DDDs in different settings were presented, e.g.,:

- evaluate the impact of information efforts and regulatory changes
- study drug exposure in relation to adverse drug reactions
- indicate over-use, under-use and misuse/abuse of drugs
- define need for further pharmacoepidemiological studies

Two sessions organized by professor Flora Haaijer-Ruskamp and professor Morten Andersen were targeted at *quality indicators and their use for improving prescribing*. The introductory session aimed at providing an overview of existing prescribing quality indicators and their use in quality improvement programs. Flora Haaijer-Ruskamp (Netherlands) gave an overview of available prescribing quality indicators and their characteristics, followed by practical examples of their use in feedback to prescribers and academic detailing in Denmark presented by Dr Janus Laust Thomsen. The advanced session explored the state-of-the-art in the area of quality indicators more in-depth with presentations on action-oriented indicators by Dr Petra Denig (Netherlands), quality indicators for antibiotic use by prof Samuel Coenen and Dr Niels Adriaenssens (Belgium) and validation of prescribing quality indicators by prof Morten Andersen, respectively.

Opportunities and challenges in *analysing expenditure in drug utilization* were explored in a session chaired by Dr Brian Godman (Italy, Sweden and UK) and Dr Sabine Vogler (Austria). The session aimed at demystifying different units of expenditure that can be used in national and cross national drug utilization studies, which include ex-factory sales, reimbursed expenditure including wholesaler and pharmacy payments as well as total expenditure including patient copayments.

Presentations adressing this issue were held by Sabine Vogler, Dr Hanna Koskinen (Finland), and Brian Godman.

The educational session on *pharmacoepidemiological tools to evaluate the impact of interventions* was chaired by prof Frank May (Australia) and Dr Mikael Hoffman (Sweden). Dr Soko Setoguch (USA) gave an overview of why pharmacoepidemiology is an important and integrated skill needed in policy interventions and presented some examples of available study designs. This was followed by presentations of three recent examples of evaluations including discussion with the audience on their pros and cons. The studies presented were “A cluster randomized controlled trial to evaluate the effects of an educational activity to change the prescribing of antibiotics in nursing homes” presented by Dr Eva Pettersson (Sweden), “The influence that electronic prescribing has on medication errors and preventable adverse drug events – An interrupted time-series study” by Peter Mol (Netherlands) and “A register-based before and after study to assess the impact of restricted reimbursement on the use of statins in Finland” by Dr Maarit Korhonen.

The final session was targeted at *biostatistical methods in drug utilization research* and chaired by Robert Vander Stichele (Belgium) and Dr Aukje Mantel-Teeuwisse (Netherlands). Three statisticians focused on common methodological problems when dealing with large sets of longitudinal drug consumption data including issues such as how to present and analyse data over time, how to deal with precision and accuracy in populations of millions of drug consumers and how to disentangle multiple levels in the data (prescriptions, prescribers or patients, institutions). The speakers were prof Douglas Steinke (UK), prof Max Petzold (Sweden) and prof Geert Molenberghs (Belgium).

3. Scientific program

The scientific program consisted of a mixture of key note lectures, presentations selected from submitted abstracts, interactive workshops and poster presentations on various aspects of drug utilization. The various themes are presented below.

3.1 Key note lecture

The key note lecture, *Better public health through pharmacoepidemiology and quality use of medicine*, was an elegant survey of the development of pharmacoepidemiology through five decades performed by the first lady of pharmacoepidemiology, professor Barbro Westerholm.



The need for pharmacoepidemiology became obvious when the Thalidomide catastrophe occurred in 1956 -1961. In order to prevent adverse drug reactions in the future, epidemiologic systems for reporting possible connections between drugs and side-effects were developed by WHO. Today there are well established WHO based centres for drug monitoring. The development of methods in drug utilization and pharmacoepidemiology in combination with the establishment of large health data registers with the possibility of record linkage between exposure and outcome has facilitated early detection of cause-effect relationship between drugs and diseases. The potentials today was illustrated with recent studies undertaken to assess the potential connection between swine-flu vaccine and narcolepsy among children.

Even if there are many reasons to be happy over the development over the last decades, there are also areas of concern. Some examples include the excessive polypharmacy and inappropriate use in the elderly as well as all drug related hospitalizations accounting for 10-30% of all admissions. Further development and research in pharmacoepidemiology and drug utilization is therefore urgently needed.

3.2 Cross national comparisons – workshop & poster session

One of the core themes of the meeting was cross national comparisons (CNC) of drug utilization. An interactive session combining lectures, posters and round-table discussions was

organized with the aim to investigate the current state of national drug utilization (DU) monitoring systems in Europe as well as provide a forum for discussion on how to proceed with CNC both from a practical and a methodological point of view.

3.2.1 Data access and comparability across healthcare systems

To answer the question on data availability and comparability, information on the current ability to collect drug consumption data and the sophistication of the DU systems on the national level was gathered with the help of key informants and contact persons using an electronic questionnaire. In an attempt to get a real picture on the ability to collect relevant data, national data on statins and proton pump inhibitors use were analyzed and compared. The data were retrieved from a previous study led by Brian Godman (in close collaboration with other members of EuroDurg and ISPE) aiming to study policies to enhance prescribing efficiency in Europe (Godman B et al. *Expert Rev. Pharmacoeconomics Outcomes Res.* 2010;10:707–722, Godman B et al. *Frontiers in Pharmacology* 2011;1:1-16). DU data were collected for the period from 2001 to 2008 from valid sources in European countries using the ATC and DDD methodology. Utilization data were analyzed alongside many supply and demand-side initiatives introduced across Europe to enhance prescribing in ambulatory care. Demand-side measures were categorized under “4Es” – Education, Engineering, Economics and Enforcement (Wettermark B, Jacobsson B, Godman B, Haaijer-Ruskamp F. *Soft regulations in pharmaceutical policymaking - an overview of current approaches and their consequences.* *Appl Health Econ Health Policy* 2009;7:1-11).

At the DUHPO conference, results from the study were presented within a special poster walk dedicated to cross national comparison of drug use. Per country posters presented utilization data on statins and proton pump inhibitors together with the 4Es summarizing national policies in the field. Great differences in the pattern and volume of statin and PPIs use were noted across different countries. The inventory of reforms showed that multiple interventions had been introduced to change prescribing patterns as well as different measures to lower generic drug prices. The measures have led to appreciable differences in drug expenditures.

Figure. CNC session with posters presenting data by country



The posters presented were also printed in a booklet offering an overview of the ability and sophistication of DU activities in 18 European countries showing attempts to enhance prescribing efficiency.

3.2.2 Workshops on opportunities and challenges in CNC

Studies on cross-national comparisons of drug use that have been conducted in previous decades have detected numerous difficulties and problems in obtaining valid, reliable and meaningful results. Researchers have been facing obstacles where in solving many of them no consensus has been reached. During the conference, seven discussion rounds covering major issues in CNC of DU were organized within the workshop, and participants were invited to take part in two different groups.

Figure. Group discussions around cross national comparisons



The topic considered by the first group was what methodology can be used to test the validity of CNC data. The group discussed what should trigger one's suspicion of invalid comparisons. It was concluded that one should always look for outliers with respect to the studied parameters and make comparisons with other nations in the same region and look at the data sources. If possible comparison with other data sources in the same country or region should be made. Also, some of the possible sources of invalid comparisons were identified: data source only covers special therapeutic, demographic or socioeconomic subgroups; economic incentives behind physician's prescribing or behind data recording; differing coverage, (e.g. +/- coverage of OTC drugs); differing versions of the ATC/DDD index and technical errors.

The second group discussed whether a common classification system for health policy initiatives, when undertaking CNCs, should be established, and if so, what should be the system to use for future studies. Within this group the following "burning" questions were raised: What different types of demand side measures have been introduced by health authorities and health insurance agencies that influence prescribing and dispensing decisions, and should interventions be categorized for comparative purposes? If so, what methods should be used to categorize them and is it necessary to develop a common classification system similar to ATC and other classification systems?

How the linkage between CNC and health outcome can be made at an international level was the theme of the third discussion group. Strict comparability of data from different countries and data sources needs to be ensured. It involves understanding concerning different underlying health systems, technical/operational systems used to record and collect data, scientific/cultural differences in the delivery of care as well as understanding of case mix and genotype of different populations being compared. In addition “sensitivity testing” of supposed outcomes is needed.

The fourth group discussed how can we proceed to install a system of CNC on regular and standardized base. The participants agreed that there is a need for CNC studies for international benchmarking from drug regulatory authorities, HTA institutions and reimbursement agencies. How could we facilitate such studies? Some of the questions for discussion concerned: creating a formal network or center(s) of excellence; establishing a regularly updated knowledge source with an inventory of existing databases, methods and standards; defining data collection templates and checklists on data coverage and validity; creating a large minimum data set with aggregate data, epidemiological measures and/or prescribing indicators. The working groups came up with the following conclusions and ideas:

A cornerstone in CNC studies is standardization. “How can we compare apples with something that is not even a fruit?” Standardization is needed, and terminology (e.g. language and pharmaceutical terms) is specifically a challenge. It was considered important to start on a small project scale (not too ambitious) with a minimum data set and expand it later. A flexible database structure would be optimal for this purpose. A collection template is required and an idea to reuse the existing ESAC template was put forward.

Whether cross national (CN) benchmarking has an additional educational value or not was a question posed to the fifth group. CN benchmarking drug use is a process of comparing various aspects of drug use among different countries, with the aim of improving drug use by adopting superior practices and education is the formal process of transmitting knowledge, skills, customs and values from one generation to another. The group discussed how CNC can accelerate international exchange of educational ideas, practices and policies, how CNC can contribute to global knowledge and internationalization of education, how CNC can increase the capacity to understand drug use patterns, determinants, quality, economic aspects of drug

use and enable predicting future use – globally. It was agreed by all participants that CNC requires methodological standardization. CNC should be taught on all levels of education including regulators/government, academia, professionals, scientists, students and patients. It should also become a part of pharmacoepidemiology syllabus but should be harmonized and include consensus based standard competences, skills and knowledge.

The possibility of using CNC to evaluate the impact of safety-related regulatory action was covered by group six. They discussed the impact evaluation of safety-related regulatory action, e.g. ‘Dear Doctor Letters’ (DHPCs) that will become mandatory in the EU from July 2012. Further on, the group brought up the following questions: Who determines appropriate outcomes? EMA, national authorities or industry? What are possible generic ‘actionable recommendations’? What are the appropriate tools; surveys (measuring knowledge, attitude/intent) and registries or dispensing/prescribing databases (measuring behavior)? Who should perform these studies? Can/will impacts be extrapolated to other countries? Should an appropriate minimal effect size be pre determined?

The seventh group discussed the topic “What therapeutic area should we focus on for the future?”. A lively discussion was held on classes of medicines that would be of interest for different stakeholders and decision makers. This included but was not limited to the following groups – high volume drugs, drugs with large variation in utilization in different countries and drugs that potentially may cause safety problems. It was also noticed that it is very important to link drug utilization data with outcome data and to explore different methods for CNC. Drug classes not suitable for CNC studies were also discussed. These include OTC drugs, drugs with many indications, orphan drugs and cancer medicines. However, some drugs from these classes may be compared under special circumstances. It was emphasized that collaboration with data or registry holders with specialist organizations, policy makers and other interested parties is of great importance. The workshop concluded that the most relevant medicines for the CNC would be drugs for elderly, biological and biosimilar products, anticoagulants, bisphosphonates, cardiology drugs and some cancer medicines (e.g. imatinib).

The great interest for the whole session towards better health outcome through cross-national-comparison (CNC) of drug utilization (DU), in which different stakeholders such as academia, medicines control agencies, reimbursement agencies, hospitals, GP/specialist and pharmaceutical companies participated, confirms that CNC of DU is a hot topic. Discussions

held within the workshop pointed out a need for standardization in all aspects of CNC. In the current era of globalization the significance of CNC of DU studies is becoming more and more important.

The national data inventory and comparative data on statins and PPIs was published in booklet distributed to all conference participants.

3.3 Innovation management and drug utilization

The challenge on rational introduction of new medicines was addressed on the session on “Innovation management and Drug utilization”. The drug market is rapidly changing. Many first-in-class and biotechnological drugs are introduced in healthcare. These medicines are often expensive, some offer benefit for the patients while others have limited efficacy or unknown safety problems. It is essential that society can afford to offer all patients the best treatment. Consequently, new drugs should be introduced systematically in healthcare. Pharmacoepidemiology and drug utilization research may offer valuable tools to improve the introduction of new medicines. These may include horizon scanning, forecasting drug utilization, monitoring patient or prescriber characteristics influencing the uptake of new drugs and analytical studies on the effectiveness and safety of drug use in real life. The session began with an introductory key-note lecture held by Dr Ken Paterson, former head of the Scottish Medicines Consortium, about the challenge of new medicines from a health policy perspective, i.e., trends in drug development, HTA and critical drug assessment in Europe. Examples of how drug utilization could contribute to a more rational introduction of new medicines was presented by Björn Wettermark and Petra Denig. Finally, professor Eric van Ganse presented the experience from France setting up a nationwide disease based register to monitor the treatment of MS.

Ken Paterson started by discussing the value of new medicines. Basically, there are two main types; those that extend choice in existing crowded areas or those that provide new options in areas with unmet needs. For extension of choice medicines it is often about putative greater benefits, e.g. in efficacy or safety and tolerability. It is important to question if the extra benefits justify the extra cost. New option medicines are often for niche indications with no real valid comparable treatments. The cost is often high and it is hard to deny patients the only existing treatment. With these medications it is easier if a subgroup of patients with the most

to gain from the medication can be defined. But who is to decide this? The amount of money in healthcare is limited; all patients cannot get all new treatments. However, new is not necessarily better and it is important to consider the cost-effectiveness. Healthcare efficiency is about getting the most gain in health for the money available; greatest good for the greatest number. Whether this is always the right thing can be questioned. No matter what, priorities have to be made in healthcare and Health Technology Assessment provides a logical framework for decisions. The extra gain of a new medication can be e.g. longer duration of life or better quality of life. The QALY (quality adjusted life year) aims to capture both in a single measure. Ken Paterson concluded by claiming that new medicines stress healthcare systems. Money needs to be transferred from one disease area to afford new innovative drugs within another disease area. But one can discuss how ethical that is. Use of generic alternatives is an important way of saving money in some areas.

Björn Wettermark talked about horizon scanning and forecasting drug utilization and expenditure. Horizon scanning is the process of identifying new medicines or new uses of existing medicines that are expected to receive market authorisation within a few years and to estimate their potential impact on patient care. The process is different in different countries. There are about twenty horizon scanning bodies in Europe. They produce early warning reports containing description of the drug and patient group, current diagnostic or treatment alternatives, current research evidence of clinical effectiveness, estimated cost for the drug and an estimate of its clinical and economic impact. The horizon scanning bodies exchange information and share experiences in the collaborative network EuroScan.

When forecasting drug expenditures, there are many factors to take into account. Both factors driving drug expenditures, e.g. ageing population and introduction of new drugs, and factors that hamper drug expenditures, e.g. patent expirations, OTC switches and reimbursement decisions. Björn Wettermark showed examples from a Swedish forecasting report of expenditures. The report is for the coming two years and is produced annually. In Sweden, access to large scale patient identity databases on dispensed drugs provides good opportunities to study e.g. prevalence and incidence. Also record linkage to other healthcare data is possible. The opportunities for forecasting in different countries depend on what kinds of data that are available.

Petra Denig talked about the possibilities to monitor the appropriateness of the prescribing of new drugs. New drugs may be restricted, e.g. to a specific group of patients with a certain

disease, with contra-indications and with warnings. The restrictions for a drug class/drug may differ between SPC, guideline recommendations and reimbursement. They are also different per country. To monitor appropriateness, different measures and methods can be used. % of prevalent and incident users per drug class can be used to monitor trends in use. % of users of a new drug without previous prescription of “old” drug can be used to monitor step in treatment. To verify target population, subgroup analysis of age and gender as compared to other drug classes can be done as well as studies of indication hierarchy, comorbidity and severity of disease in treated patients.

Furthermore, Petra Denig presented results from different prescribing studies. A study of statin prescribing according to age/gender and indication hierarchy (Wallach Kildemoes H et al., 2011) showed that statins were prescribed for clear indications in men but more often for vague indications in women. Follow-up studies of ARBs showed that its restrictions were not followed. ARBs were not only used as a second line treatment in hypertension (Greving JP et al., 2005) and they were prescribed to all hypertensive patients, not only the recommended groups (Greving JP et al., 2004).

Finally, Eric Van Ganse talked about his experiences from France of disease-based registries to monitor utilization and outcome and gave advice on the construction of a register. He pointed out that before starting a registry, one to three years of work with determining and specifying what data to be collected is needed. Primary outcomes should be focused on specific measures so the registry does not become too wide. An example of a specific measure is serious adverse events. Follow-up can later be performed in different ways depending on the receivers focus, e.g. economy. Registries must be computerized/web-based and regularly updated. Data must be included in a standardized way and it must be possible to add additional external data. Another important factor that contributes to a successful registry is to involve experts throughout the process. Eric Van Ganse concluded by saying that there is a high interest in exposure registries and told about “Tysedmus”, a risk minimization project to actualize risk-benefit profile and safety profile of natalizumab in French MS patients.

3.4 Adherence in drug utilization research

Adherence to medications is essential for therapeutic success. Professor Bernard Vries (Belgium) was the key note speaker in a session on adherence also including four

presentations selected from submitted abstracts. He gave a nice overview of the state of the art including terminology and the pros and cons using different methods to monitor adherence.

Adherence to medications may be defined as “the process by which patients take their medications as prescribed” and it is composed of three parts: initiation, discontinuation and implementation. Initiation occurs when the patient takes the first dose of a prescribed medication. Discontinuation occurs when the patient stops taking the prescribed medication. Implementation is the extent to which a patient’s actual dosing history corresponds to the prescribed dosing regimen, from initiation until discontinuation of dosing. Persistence may be defined as the length of time between initiation and discontinuation of dosing.

Compliance studies may be carried out with different methodologies including from electronic monitoring devices, pill-counts, questionnaires and interviews. Bernard Vries emphasized that pill-counts and self-reports, such as patient diaries, have a tendency to overestimate adherence. By using electronically compiled dosing histories large cohorts of patients may be followed determining persistence and adherence and which factors that are associated with poor compliance. Bernard Vries did not only showed that about 40% of the patients treated for chronic diseases have discontinued the prescribed drugs after 12 months but also that less than 20 % of the patients had a correct dosing regimen after 12 months. Too short dosing intervals increase the risk for toxicity and side effects and too long dosing intervals could lead to loss of effectiveness.

This lecture implies the importance for clinicians not only to ask the patient for persistence to medication but also to ask for how the medication is taken before just changing the therapy.

3.5 Validation studies of data and indicators

The session on validity aimed at presenting important issues of data validity in pharmaco-epidemiology, and to discuss four studies selected from submitted abstracts analysing the agreement between data collected from different sources. The introductory key note lecture was held by professor Jesper Hallas (Denmark). He began by saying that validity comes from the Latin word “valere”, which means “be strong”, and then he described the concepts of internal and external validity. The process from drug prescribing to ingestion was illustrated

by the three events; prescribing, dispensing and ingestion, where each step can be estimated by a proxy. Prescribing can be estimated by data from a physician administrative system, dispensing can be assessed using data from a pharmacy-based prescription database and ingestion can be estimated by information from a patient source, e.g. by an interview.

The second step in the process, dispensing, reflects primary non-compliance. A much quoted study about primary non-compliance was carried out by Beardon et al. and was published in BMJ 1993. In general, primary non-compliance was about 3-8 % and thus no serious matter. There were, however, substantial differences between different drug classes, with contraceptives being an outlier with about 25 % of all prescriptions not dispensed. In the study physician database were used as a measuring point and pharmacy database was used as a golden standard and a measuring point assuming these proxies had no errors.

In a study by Olesen C et al. 2002 measuring internal validity, drug use reported by interview was compared to data retrieved in database. There were both over-reporting and under-reporting. Analgesics were heavily over-reported in interviews while antibiotics were under-reported. There are many studies on agreement between prescription data sources. Some conclusions are that no true gold standards exist, they are all alloys. Non-compliance is substantial and is difficult to ascertain, and databases may have important limitations, e.g. absence of non-subsidized prescription medication and OTC drugs.

Jesper Hallas concluded the session asking which data source the audience would recommend for drug utilization studies and answered that there was no golden standard and sources should be carefully selected depending on the context

3.6 Drug utilization research in benefit-risk evaluation

The importance of drug utilization research for benefit-risk evaluation was discussed in a key note lecture held by Dr Xavier Kurz from EMA. In the old model of pharmacovigilance the regulator places obligations on the pharmaceutical industry, waits for results from clinical studies and then assesses these. In the new model of pharmacovigilance, the regulatory decision-making is based on collection and assessment of all data including industry studies, academic studies, public authority studies and data from real-life health outcomes making it possible to study e.g. patterns of drug use in real life situations, characteristics of patients

starting on a new drug and evaluation of benefit/risk. Continuous evaluations are done throughout the whole lifecycle of medicines. The session also described several important roles of drug utilization data in benefit-risk evaluation, including detection of abuse, misuse or other use affecting safety, planning pharmacoepidemiological studies, public health impact of adverse drug reactions and risk minimization measures.

Xavier Kurz also described the role of European Medicines Agency (EMA) as the coordinator of Pharmacoepidemiological Research on Outcomes of Therapeutics by a European Consortium (PROTECT) that comprises a programme to address limitations of current methods in the field of pharmacoepidemiology and pharmacovigilance. The goal is to strengthen the monitoring of the benefit-risk of medicines in Europe by developing a set of innovative tools and methods that will enhance early detection and assessment of adverse drug reactions from different data sources. These methods will be tested in real-life situations in order to provide all stakeholders with accurate and useful information supporting risk management and continuous benefit-risk assessment. A methodological framework for pharmacoepidemiological studies will be developed and tested to enable data mining, signal detection and evaluation in various types of datasets, including data of spontaneous reports, registries and other electronic databases. He concluded the session emphasizing that drug utilization data are today underused, however the use of these data are increasing and may play an important role in key aspects of the drug regulatory process.

The importance of drug utilization research for pharmacovigilance and risk management was also addressed in a subsequent workshop. In the workshop several important roles of drug utilization data in benefit-risk evaluation and these were illustrated by examples. To name a few; detection of abuse, misuse or other use affecting safety, planning pharmacoepidemiological studies, public health impact of adverse drug reactions and risk minimization measures.

The benefit-risk ratio of a drug may change when the drug is available on the market and this scenario was illustrated by the case history of Avandia. The antidiabetic drug rosiglitazone was associated with increased risk of heart failure and restricted to second-line treatment. Accumulated data from a variety of sources supported an increased cardiovascular risk of rosiglitazone and the benefits did no longer outweigh the risk. EMA recommended a suspension. This case shows that measurement of drug utilization patterns is essential for the

benefit-risk evaluation of marketed drugs and drug utilization studies can be an effective tool to measure directly the performance of risk minimization measurements.

3.7 Epidemiological measures of drug use in patient identity databases

This workshop was held by prof Jesper Hallas (Denmark) and prof Morten Andersen (Denmark/Sweden), who enthusiastically talked about the two very important epidemiological measures of drug use; persistence and incidence, and how they can be used when working with dispensing data. Prevalence can be measured through point prevalence (the proportion of a population e.g. uses the drug on a given point in time) or period prevalence (the proportion of a population that e.g. uses a drug within a period). The disadvantage of using point prevalence is that it may depend on e.g. seasonal variations, while period prevalence includes incident and short-term users. Incidence rate is the number of drug users divided by the person-time at risk that gave rise to the new cases. The disadvantage of using this measure is that it can overestimate the true value. Point prevalence and incidence are linked to each other through the estimate of duration but is hard to interpret and has the same disadvantages as point prevalence. Another measure discussed was the waiting time distribution, described as the distribution of time until the first prescription for users of specific drugs within a specific time window. Prevalence of drug use can also be determined by incidence of use, discontinuation of use and mortality among users. The workshop presented aggregated DDD-based consumption figures with a series of questions on prescribing behavior, prescribing quality, public health relevance, and dynamics of the drug user population, and the listeners had to figure out answers to which measures should be preferred, how should the measure be interpreted and how do they contribute to our understanding of drug utilization patterns.

3.8 Generics in Drug Utilization research

The session consisted of a key note lecture by prof Steven Simoens (Belgium) followed by four presentations selected from submitted abstracts. It gave a good overview of how different countries treat the topic generics. There are big differences between how much countries focus on generics. This may partly depend on the noticeably marked price differences. As an example, in France and Germany generics have substantially higher prices than in Scandinavia. A consequence of a low use of generics is higher healthcare costs. This may be observed when studying the drug treatment in the elderly. The European population is getting

older resulting in increasing drug expenditure. Many elderly use a lot of different drugs and may not be able to cover their increasing medical costs. This is likely to result in a lower compliance to the prescribed regimen, subsequently resulting in higher total healthcare spending. Through drug utilization research such negative aspects may be identified and interventions should follow. The session gave an insight of the prescribing of generics in Germany, the multiple initiatives done in Scotland to appreciably improve prescribing efficiency for the statins and PPIs, and an analysis of ambulatory care physicians in terms of their age, sex, patient numbers on whether they were more likely to prescribe originator statins than generics, and of the impact of Drug Price Reducing Policy on the use of originator and generic ACE-inhibitors and ARBs for treatment of outpatients with hypertension in Southern Taiwan.

3.9 Interventions to improve Drug Utilization

3.10 The future of quality use of medicine:

The conference ended with a key lecture held by professor Bert Leufkens on the future of quality use of medicines followed by recent examples of academic detailing, feedback and quality incentives from Sweden and Australia.

Bert Leufkens referred to the many dimensions of drug utilization research. Regarding dose regimen many drugs are not well dosed in studies which complicates the interpretation of results in comparative studies. Therapeutic indications for drugs changes over time and few drugs exist with only one indication. Therefore it is important to connect a drug to a diagnosis when analysing...

It is important to reflect on the methods used in studies, but sometimes we focus too much on to comment on the flaws. This makes policymakers uncertain about data's value.

Björn Wettermark described the Swedish healthcare system...

4. Literature Review on cross-national comparison of Drug Utilization activities

Part of the preparatory work for the DUHPO meeting included a structured literature review on scientific articles comparing drug utilization across different (European) countries published from January 1, 2000 to June 30, 2011.

The review included studies:

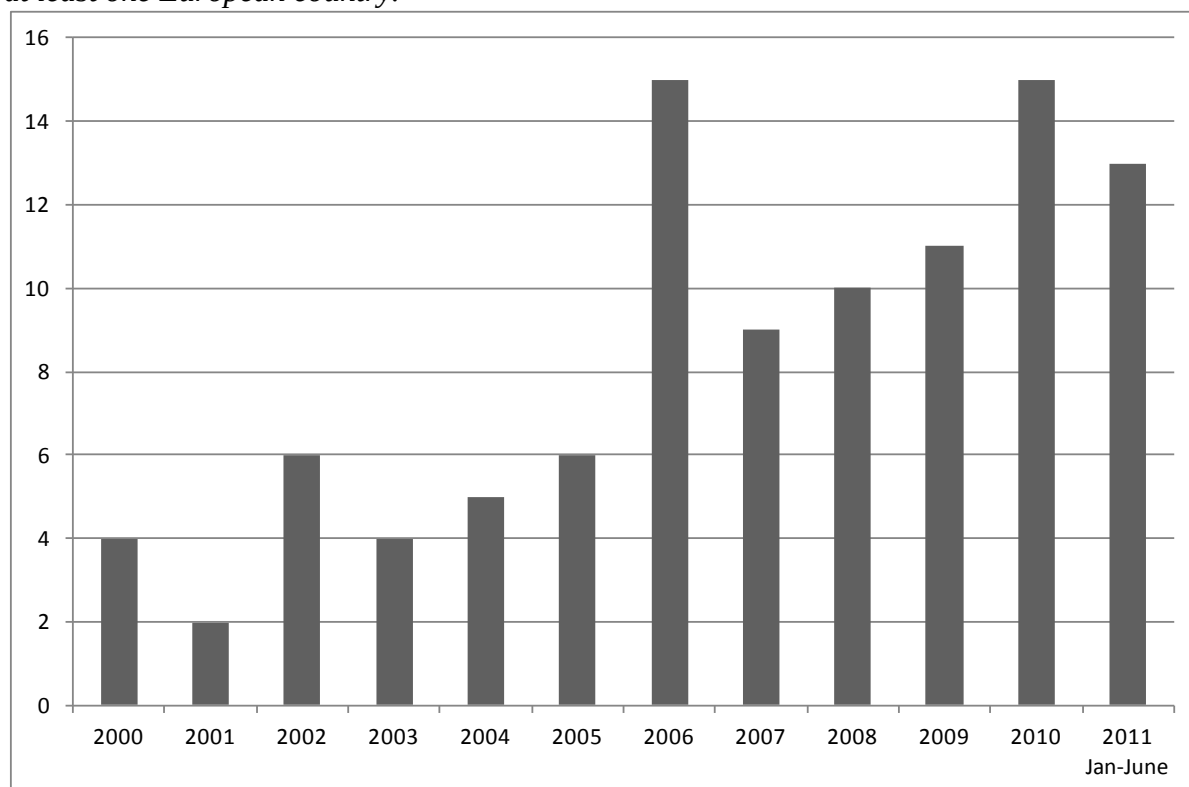
- showing drug utilization data in volume or expenditure
- including at least two countries out of which one was European
- using a methodology facilitating cross national comparison
- published in a peer review journal including accepted available on Internet
- published in English

Exclusion criteria were:

- studies with data from only drug use in individual hospitals
- studies only focusing on drug use in nursing homes

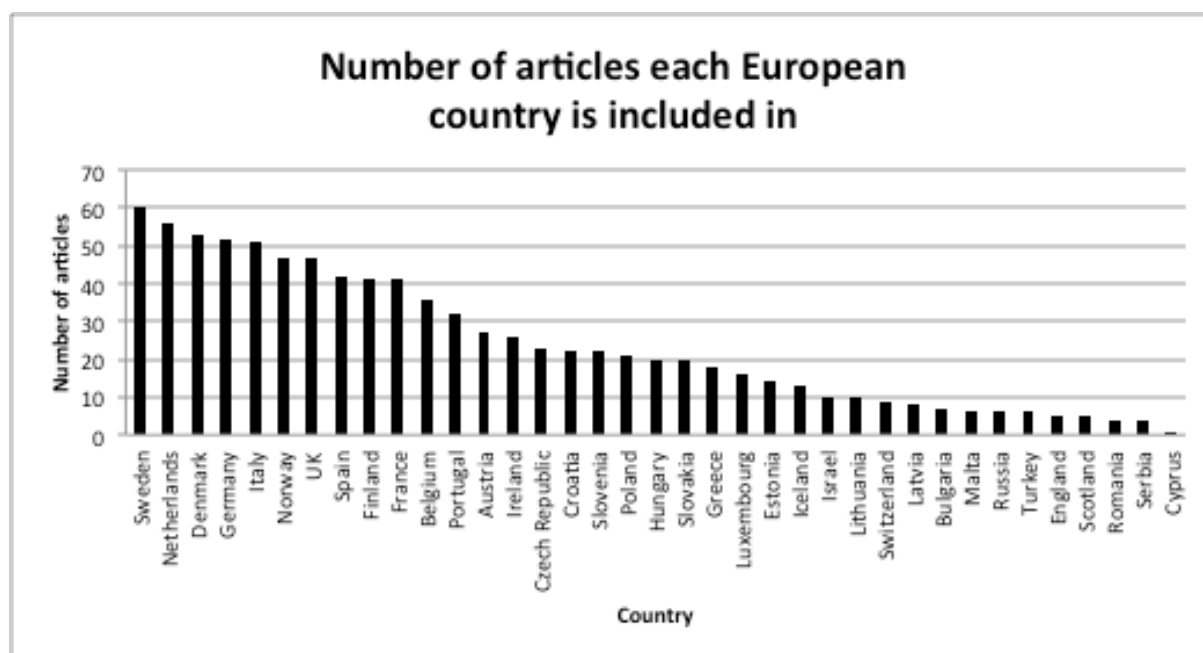
The literature search resulted in a total of 100 scientific papers including papers added by the scientific committee and not identified in the initial medline search. The result showed that the number of published articles increased over time (Figure below). An exceptionally high number of papers were published in 2006, partly due to the large number of publications from the ESAC project.

Figure. Number of scientific publications with cross national comparisons per year including at least one European country.



A total of 37 different European countries had participated in at least one study (see Figure below). The country most frequently participating in CNC was Sweden followed by the Netherlands, Denmark, Germany and Italy, all included in more than half of all CNC studies.

Figure 2. Number of CNC studies each European country is included in.



Countries outside Europe included in the CNC studies were the United States (included in 10 studies), Australia (9), Canada (9), New Zealand (3), Japan (1) and South Africa (1).

A variety of datasources were used from administrative databases on reimbursement for drugs dispensed in ambulatory care to disease based registries and questionnaires to physicians and patients. Some studies were based on sales data collected from IMS.

The most commonly studied therapeutic area was antibiotics followed by cardiovascular drugs. Most studies included the general population in each country but some studies were restricted to, e.g. children and restricted populations.

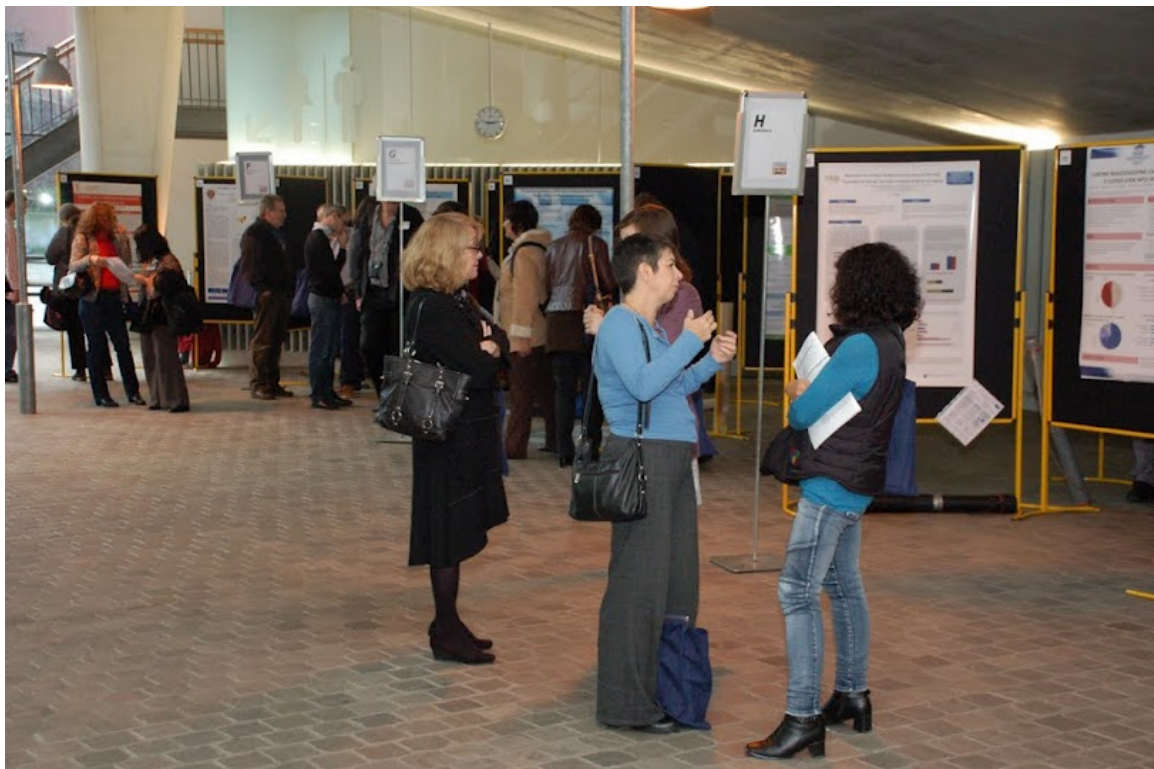
In 60 studies, it was clearly presented that the ATC-system was used for drug classification. Most studies focused on volumes with DDD or DDD/TID being used in approximately half of all studies. Prevalence in terms of number of patients was only used in four studies. Expenditures were presented in nine studies.

The result was published in booklet distributed to all conference participants.

Submitted abstracts

The call for abstracts resulted in 122 submitted abstracts with 59 of them being new abstracts. Sixteen were selected for oral presentation. The remaining were presented during the CNC poster walk on Thursday or? during the special poster walk session on Friday, where all authors were offered the opportunity to present their work. Among the abstract submissions, the best oral presentation and the best poster presentation were selected and awarded with a reimbursement of their registration fee (see DUHPO awards below).

Figure. Poster session



DUHPO awards

DUHPO meeting awards were given to best oral and poster presentations, respectively.

Nominations for the oral prize were:

- ❖ Elisabetta Poluzzi (Italy)
Drug utilisation of antidepressants in General Practice: choice of drugs and adherence in an Italian region
- ❖ Catherine Sermet (France)
Explaining the reasons why French patients are being prescribed more originator statins than generic
- ❖ Magnolia Cardona-Morrell (Au)
Six-month impact evaluation of a prescribing improvement intervention for cardiovascular disease management in Australian general practice

Best oral presentation winner:

Maria Matuz, Ria Benko, Monique Elseviers, Edit Hajdu, Peter Doro, Reka Viola, Gyongyver Soos (Hungary)
Dosage form data used for estimating pediatric antibiotic use

DUHPO meeting award for **best poster** presentation

Nominations:

- ❖ Milica Paut Kusturica (Serbia)
Is there a difference in antibiotic use between urban and rural communities in Serbia?
- ❖ Johanita Burger (South Africa)
Identifying South African patients with metabolic syndrome using medicine claims data
- ❖ Danny Van heusden (Belgium)
AlterMED: Attitude, knowledge and use of alternative medicine

Best poster award winner:

Shuk-Li Man, Irene Petersen, Mary Thompson, Irwin Nazareth (UK)
Discontinuation of antiepileptic drugs in pregnancy; a study in The Health Improvement Network (THIN)

5. Evaluation of the meeting

Shortly after the end of the DUPHO meeting a web questionnaire was sent out to the 145 conference participants including speakers and members of the scientific committee. All respondents were asked about their previous experience of DURG/ISPE conferences and to rate the scientific content and relevance as well as the social program and the practical arrangements. Furthermore, they were asked to rate all the different sessions and to give individual comments and suggestions for future meetings. All ratings were done on a ten-grade scale with 10 being most positive.

A total of 104 (72%) responded to the questionnaire with academia being the most common affiliation with 52% of all participants. Around half of all participants (49%) had participated in a previous meeting held by ISPE and/or EuroDURG. The mean rating of the value of the conference was between 8 and 9 for all general aspects of the conference (scientific content, relevance for work, social program, establishing contact/networking, practical arrangements).

All topics of the conference were appreciated with mean ratings between 7-10. A lot of ideas of topics for future conferences were suggested. Some examples are electronic decision support systems, risk benefit evaluation of medicines by patients, different data sources for drug utilisation research and their strength and limitations, drug use in hospitals, how to plan a study, drug use in children and the elderly, methodologies for changing prescriber behavior, determinants/models/theories of suboptimal prescribing behaviour

Appendix 1. Scientific program

WEDNESDAY 30-11-2011

13.30 – 14.15 W1 – EDUCATIONAL SESSION Drug utilization research as a tool for health policy

Room: Tassis **Chair:** Björn Wettermark

Aim: To give an overview of pharmacoepidemiology and drug utilization research in health policy and to explain the skills needed and the expected outcome from the different course sessions.

- Introduction** Definitions of research fields and methodological framework
Robert Vander Stichele (Be)
- 13.30 – 13.35** Welcome to Antwerp and to the EuroDURG/ISPE meeting
Monique Elseviers (Be)
- 13.35 – 14.00** What is drug utilization research and why is it important in policymaking?
Robert Vander Stichele (Be)
- 14.00 – 14.15** The skills needed in DUR – Expected course outcomes
Björn Wettermark (Se)

14.15 – 15.45 W2 – EDUCATIONAL SESSION Classification systems and measurement units of utilization

Room: Tassis **Chair:** Hanne Strøm

Aim: To give an overview of classification systems for medicinal products. To describe the Anatomical Therapeutic Chemical (ATC) classification system and the unit of measurement (DDD), and how to use this methodology.

- 14.15 – 14.45** Overview of classification systems with focus on ATC
Hanne Strøm (No)
- 14.45 – 15.15** The concept of the Defined Daily Dose (DDD)
Hege Salvesen Blix (No)
- 15.15 – 15.45** Application of ATC/DDD in health policy and drug utilization
Solveig Sakshaug (No)

16.15 – 17.45 W3 – EDUCATIONAL SESSION Quality indicators and their use for improving prescribing – An introduction

Room: Tassis **Chair:** Flora Haaijer-Ruskamp – **Co-chair:** Morten Andersen

Aim: To provide an overview of existing prescribing quality indicators and their use in quality improvement programs (educational session).

- 16.00 – 16.30** Prescribing quality indicators – Overview of available prescribing quality indicators and their characteristics
Flora Haaijer-Ruskamp (NI)
- 16.30 – 16.45** Practicing with PQI indicators – Interactive session with participants
Flora Haaijer-Ruskamp (NI)
- 16.45 – 17.15** Use of quality indicators in practice
Janus Laust Thomsen (Dk)
- 17.15 – 17.45** Practicing with feedback – Interactive session with participants
Janus Laust Thomsen (Dk)

[Back to the program at a glance](#)

THURSDAY 01-12-2011

09.00 – 10.30 T1A – ADVANCED EDUCATIONAL SESSION Exploring units of expenditure in drug utilization studies

Room: *Dürer* **Chair:** [Brian Godman](#) – **Co-chair:** [Sabine Vogler](#)

***Aim:** To demystify the many different units of expenditure that can be used in national and cross national drug utilisation studies, which include ex-factory sales, reimbursed expenditure including wholesaler and pharmacy payments as well as total expenditure including patient copayments.*

09.00 – 09.10 Introduction

[Brian Godman](#) (UK)

09.10 – 09.40 Explaining the components of pharmaceutical expenditure – Overview of different policies across Europe

[Sabine Vogler](#) (Austria)

09.40 – 10.10 Measuring and comparing pharmaceutical expenditures – Considerations based on national and European experiences

[Hanna Koskinen](#) (Fi)

10.10 – 10.30 General questions and conclusions for the future

[Brian Godman](#) (UK)

09.00 – 10.30 T1B – ADVANCED EDUCATIONAL SESSION Prescribing quality indicators – Advanced session

Room: *Tassis* **Chair:** [Morten Andersen](#) – **Co-chair:** [Flora Haaiker-Ruskamp](#)

***Aim:** To present recent developments in PQI, provide a deeper knowledge on indicators and enable participants to implement this in their own context.*

09.00 – 09.30 Beyond the hitlist – Towards more tightly linked and action-oriented indicators

[Petra Denig](#) (NL)

09.30 – 09.50 International quality indicators for outpatient antibiotic use – ESAC drug-specific indicators

[Samuel Coenen](#) (Be)

09.50 – 10.10 ESAC disease-specific indicators

[Niels Adriaenssens](#) (Be)

10.10 – 10.30 How do we select the most relevant measures of prescribing quality?

[Morten Andersen](#) (Dk)

11.00 – 12.30 T2A – ADVANCED EDUCATIONAL SESSION Using pharmaco-epidemiological tools to evaluate the impact of interventions

Room: *Dürer* **Chair:** [Frank May](#) – **Co-chair:** [Björn Wettermark](#)

***Aim:** To explore and analyse various methodological issues in evaluating the effects of interventions using drug utilization data.*

11.00 – 11.30 Overview of available study designs to analyse the impact of interventions

[Soko Setoguchi](#) (USA)

11.30 – 12.20 Presentations of three recent examples of evaluations including discussion with the audience on their pros and cons

1. A cluster randomized controlled trial to evaluate the effects of an educational activity to change the prescribing of antibiotics in nursing homes.

[Eva Pettersson](#) (Se)

2. The influence that electronic prescribing has on medication errors and preventable adverse drug events – An interrupted time-series study

[Peter Mol](#) (NL)

3. A register-based before and after study to assess the impact of restricted reimbursement on the use of statins in Finland

[Maarit Korhonen](#) (Fi)

12.20 – 12.30 Summary and conclusions, key learnings

11.00 – 12.30 T2B – ADVANCED EDUCATIONAL SESSION Biostatistical methods in drug utilization research

Room: Tassis **Chair:** Robert Vander Stichele – **Co-chair:** Aukje Mantel-Teeuwisse

***Aim:** Three eminent statisticians will focus on common methodological problems when dealing with large sets of longitudinal drug consumption data. How to present and analyse data over time? How to deal with precision and accuracy in populations of millions of drug consumers? How to disentangle multiple levels in the data (prescriptions, prescribers or patients, institutions)?*

11.00 – 11.30 Time series analysis
Douglas Steinke (UK)

11.30 – 12.00 Accuracy and precision in high volume data sets
Max Petzold (Se)

12.00 – 12.30 Multilevel analysis in drug utilization data
Geert Molenberghs (Be)

[Back to the program at a glance](#)

13.30 – 14.15 T3 – KEY LECTURE Better public health through pharmaco-epidemiology and quality use of medicine

Room: Tassis **Chair:** Björn Wettermark – **Co-chair:** Frank May

***Aim:** To set the scene of the conference and illustrate the importance of drug utilization research in healthcare policymaking to improve the use of medicines in the society.*

13.30 – 13.40 Welcome
Monique Elseviers (Be)
History of the meeting
Robert Vander Stichele (Be)
The connection with pharmaco-epidemiology and ISPE
Frank May (Australia)

13.40 – 14.15 Key lecture: Better public health through pharmacoepidemiology and quality use of medicine
Barbro Westerholm (Se)

14.15 – 17.45 T4 – WORKSHOP Towards better health outcome through cross national comparison of drug utilization

Room: Tassis **Chair:** Monique Elseviers – **Co-chair:** Vera Vlahović-Palčevski

***Aim:** To demonstrate the possibilities and limitations of European cross national comparison (CNC) studies and associated health policy initiatives and to discuss future methodology in this field.*

14.15 – 14.45 Introduction

Room: Tassis

- State-of-the-art of cross national comparison (CNC) studies
- Studies assessing the impact of health policy initiatives
- Initiatives to evaluate difference in DU in relation to health outcome
- Key opportunities and challenges for the future

Björn Wettermark (Se)

14.45 – 15.45 CNC Poster walk (combined with coffee break)

Room: Pretenkabinet and Scaldis

16.15 – 17.30 Discussion rounds on CNC methodology

Room: See color code

1. What methodology can be used to test the validity of CNC data?
Monique Elseviers (Be) – Jesper Hallas (Dk)
2. Should we establish a common classification system for health policy initiatives when undertaking CNCs? If so, what should be the system to use in future

studies?

Brian Godman (UK) – Flora Haaïjer-Ruskamp (NL)

3. How can the linkage between CNC and health outcome be made at the international level?

Frank May (Australia) – Alison Bourke (UK)

4. How can we proceed to install a system of CNC on a regular and standardized base?

Morten Andersen (DK) – Hanne Strøm (NO)

5. Does CN benchmarking have an additional educational value?

Vera Vlahović-Palčevski (HR) – Eric Van Ganse (FR)

6. Cross national comparisons to evaluate the impact of safety-related regulatory action across EU member states

Peter Mol (NL) – Ulf Bergman (SE)

7. What therapeutic area should we focus on for the future?

Björn Wettermark (SE) – Jolanta Gulbinovic (LT)

17.30 – 18.15 Round table: Advantages and disadvantages of CNC for future health policy

Room: Tassis

Robert Vander Stichele (BE) (discussion leader)

Panel: **Jesper Hallas (DK) – Flora Haaïjer-Ruskamp (NL) – Alison Bourke (UK) – Hanne Strøm (NO) – Eric Van Ganse (FR) – Ulf Bergman (SE) – Jolanta Gulbinovic (LT)**

[Back to the program at a glance](#)

FRIDAY 02-12-2011

09.00 – 10.30 F1 – KEY LECTURE Innovation management and drug utilization

Aula: B004 [Chair: Björn Wettermark](#)

Aim: To explore how pharmacoepidemiology and drug utilization may be valuable tools to improve the entry of new medicines in healthcare systems.

09.00 – 09.20 Rational use of new medicines – A challenge for health policy

Ken Paterson (UK)

09.20 – 09.40 Horizon scanning and forecasting drug utilization and expenditure

Björn Wettermark (SE)

09.40 – 10.00 Monitoring the appropriateness of the prescribing of new drugs

Petra Denig (NL)

10.00 – 10.20 Disease-based registries to monitor utilization and outcome

Eric Van Ganse (FR)

10.20 – 10.30 Summary and conclusions

11.00 – 12.30 F2A – KEY LECTURE AND SELECTED ABSTRACTS Adherence in drug utilization research

Room: Prentenkabinet [Chair: Monique Elseviers](#) – [Co-chair: Eric Van Ganse](#)

Aim: This session with selected abstracts on Adherence will start with a key lecture on the use of large databases for adherence studies and the link between efficacy and effectiveness.

11.00 – 11.30 The use of large databases for adherence studies and the link between efficacy and effectiveness

Bernard Vrijens (BE)

11.30 – 12.30 Oral presentation of selected abstracts

11.30 – 11.45 F2A01 Drug utilisation of antidepressants in General Practice: choice of drugs and adherence in an Italian region

Elisabetta Poluzzi (IT)

11.45 – 12.00 F2A02 Are refill adherence measures associated with glycemic control in patients with diabetes? Looking at different measures and cutpoints for non-adherence

Jaco Voorham (NL)

12.00 – 12.15 **F2A03 Experience with adherence to anti-diabetic medication in Zagreb, Croatia**

Josip Čulig (Hr)

12.15 – 12.30 **F2A04 Nurse-led education and counseling to enhance adherence to phosphate binders**

Yoleen Van Camp (Be)

11.00 – 12.30 F2B – KEY LECTURE AND SELECTED ABSTRACTS Validation studies of prescription data and indicators

Aula: B004 [Chair: Morten Andersen](#) – Co-chair: [Alison Bourke](#)

***Aim:** To present important issues of data validity in pharmacoepidemiology, in particular to what degree dispensing data reflects actual drug use, possible biases and limitations. Additionally to present results from studies that compare different data sources or assess the validity of quality indicators.*

11.00 – 11.30 **Validity of data sources in pharmacoepidemiology**
Jesper Hallas (Dk)

11.30 – 12.30 **Oral presentation of selected abstracts**

11.30 – 11.45 **F2B01 Predictors of antipsychotic prescription in a Northern Italian District (Bologna)**

Carlo Piccinni (It)

11.45 – 12.00 **F2B02 Dosage form data used for estimating pediatric antibiotic use**

Maria Matuz (Hu)

12.00 – 12.15 **F2B03 Drug treatment in patients with newly diagnosed unprovoked seizures/epilepsy**

Linnea Karlsson (Se)

12.15 – 12.30 **F2B04 Prevalence and incidence of end-stage renal disease (CKD5) in patients with diabetes mellitus type 1 and 2 in Flanders, Belgium: a case-population study**

Gert A. Verpooten (Be)

[Back to the program at a glance](#)

13.15 – 14.45 F3 – POSTER SESSION

Aula: Rector Dhanis

***Aim:** To attend a guided poster walk, visiting selected posters with a short presentation by the author and a guided discussion about the content.*

15.00 – 15.45 F4 – KEY LECTURE Drug utilization research in benefit-risk evaluation

Aula: B001 [Chair: Robert Vander Stichele](#)– [Co-chair: Ken Paterson](#)

***Aim:** .To describe the potential contribution of Drug Utilisation research to Pharmacovigilance, Pharmacoepidemiology, risk management and the overall benefit-risk evaluation of medicines.*

15.00 – 15.45 **Measuring drug utilization – Importance in pivotal aspects of Pharmaco-epidemiology**

Xavier Kurz (Be)

16.15 – 17.45 F5A – WORKSHOP Drug utilization data in pharmacovigilance and risk management – A new dimension to the analysis of risk at the population level

Aula: B002 **Chair:** Elisabetta Poluzzi – **Co-chair:** Ulf Bergman – **Co-chair:** Cosimo Zaccaria – **Co-chair:** Giampiero Mazzaglia

***Aim:** To define the possible roles of drug utilisation data in the interpretation of pharmacovigilance signals and in the initiatives for risk management.*

16.15 – 16.30 Introduction – The role of drug utilization data in pharmacovigilance from the Regulatory Agency perspective

Xavier Kurz (Be)

16.30 – 16.45 Introduction to group work – Invitation to discuss different approaches to use drug utilization data in pharmacovigilance. Three main focuses:

1. Interpretation of differences among countries and time-trends in spontaneous reports
2. Calculation of the reporting rate
3. Assessment of the level of risk in the population (risk management)

16.45 – 17.15 Group work – Exploration of the approaches cited above by taking into account the following elements:

1. On the basis of drugs of interest (e.g., drugs used only by reimbursed prescriptions, drug with multiple ways of supply) and countries involved in the analysis (different quality of DU data), a specific source of data (or more than one) will be needed (e.g., sales data, hospital data).
2. Indicators to be used in the analysis of ADR/DU will be proposed (e.g., minimal rate, incidence, prospective risk);
3. Limitations of each type of source and indicator should be acknowledged

17.15 – 17.45 Discussion – Each group will present the strategies developed during the work session and will propose possible application to emergent safety issues.

16.15 – 17.45 F5B – WORKSHOP Epidemiological measures of drug use in patient identity databases

Aula: B003 **Chair:** Morten Andersen (Dk) – **Co-chair:** Maarit Korhonen (Fi)

***Aim:** To give participants an understanding of epidemiological measures of drug use and their interpretation in different contexts (workshop).*

16.15 – 16.30 Incidence and prevalence of drug use – A brief overview

- Definitions of epidemiological measures of drug use
- How can they be estimated from dispensing data
- The relation between incidence, prevalence and duration
- The waiting time distribution
- Dynamic pharmacoepidemiologic model of drug use

Jesper Hallas (Dk)

Morten Andersen(Dk)

16.30 – 17.15 Group work

Selected examples on incidence and prevalence of drug use and traditional aggregated DDD-based consumption figures are presented

with a series of questions on prescribing behaviour, prescribing quality, public health relevance, and dynamics of the drug user population.

- Which measures should be preferred for different questions
- How are the measures interpreted
- How do they contribute to our understanding of drug utilisation patterns

17.15 – 17.45 Presentation of answers and discussion

SATURDAY 03-12-2011

09.00 – 10.30 S1A – KEY LECTURE AND SELECTED ABSTRACTS Drug utilization research studies and generics

Room: *Dürer* **Chair:** Brian Godman – Co-chair: Saskia van der Erf

***Aim:** To potentially seek further ways to enhance the utilization of generics at increasingly lower costs as all health authorities and health insurance agencies across Europe try to maintain the European ideals of comprehensive and equitable healthcare in the face of growing pressure on resources.*

09.00 – 09.05 Introduction

Brian Godman (UK)

09.05 – 09.40 Drug utilization research studies and generics

Steven Simoens (Be)

09.40 – 10.30 Oral presentation of selected abstracts

09.40 – 09.55 S1A01 Prescribing of Generics in Germany at a Glance

Ingrid Schubert (De)

09.55 – 10.10 S1A02 Multiple initiatives continue to enhance the prescribing efficiency for the PPIs and statins in Scotland

Iain Bishop (UK)

10.10 – 10.25 S1A03 Explaining the reasons why French patients are being prescribed more originator statins than generic

Catherine Sermet (Fr)

10.25 – 10.40 S1A04 The Impacts of Drug Price Reducing Policy on Utilisation of Generic and Branded Angiotensin-converting Enzyme Inhibitors and Angiotensin Receptor Blockers for Treating Hypertensive Outpatients in Southern Taiwan

Li-Chia Chen (UK)

09.00 – 10.30 S1B – KEY LECTURE AND SELECTED ABSTRACTS Interventions to improve drug utilization

Room: *Tassis* **Chair:** Frank May – **Co-chair:** Flora Haaijer-Ruskamp

***Aim:** To give an overview of how pharmacoepidemiology and drug utilization research has contributed to the current knowledge on the effectiveness of interventions and discuss examples of ongoing studies in the field.*

09.00 – 09.20 State-of-the-art in research on the impact of interventions

Soko Setoguchi (USA)

09.20 – 10.20 Oral presentation of selected abstracts

09.20 – 09.35 S1B01 Six-month impact evaluation of a prescribing improvement intervention for cardiovascular disease management in Australian general practice

Magnolia Cardona-Morrell (Au)

09.35 – 10.50 S1B02 Impact of safety-related regulatory action on patterns of drug use in ambulatory care in The Netherlands.

Peter Mol (NI)

10.50 – 11.05 S1B03 Interrupted time series analysis of the impact of antibiotic sales restrictions in Chile, Colombia and Venezuela

Veronika J. Wirtz (Mx)

11.05 – 10.20 S1B04 Analysis of the impact of progressive delisting phlebotonics on prescription rates: a times-series analysis for France 1999-2009

Catherine Sermet (Fr)

10.20 – 10.30 Summary: What have the studies added to the scientific body

11.00 – 12.25 S2 – KEY LECTURE The future of quality use of medicines – From measurements to implementation

Room: Tassis **Chair:** Aukje Mantel-Teeuwisse – **Co-chair:** Robert Vander Stichele

***Aim:** To provide a historical overview of drug utilization research and its aims. To make participants realize that thinking before doing is important in drug utilization research to obtain the best results for public health. To show best practices how drug utilization can add to improvement of quality of drug use.*

11.00 – 11.05 Introduction

11.05 – 11.45 Quality thinking, learning and doing

Bert Leufkens (NI)

11.45 – 12.00 The Swedish model of financial incentives and self-assessment (tbc)

Björn Wettermark (Se)

12.00 – 12.15 Academic detailing – Changing knowing into doing

Frank May (Australia)

12.15 – 12.25 Wrap up and future outlooks

Bert Leufkens (NI)

[Back to the program at a glance](#)

Joint educational course
and scientific meeting

**Better public health through
pharmacoepidemiology and
quality use of medicine**



The European branch of the
Special Interest Group for Drug
Utilization Research (SIGDUR)



30/11-03/12/2011

Hof Van Liere,
University of Antwerp

EuroDURG

April 18, 2012

Financial Outcome of the meeting

Final situation April 14, 2012
Meeting number UA SC201117

Booking year 2011

Income	42 661.00
Expenditures	38 787.34

Booking year 2012

Income	11 020.00
Expenditures	17 155.51

TOTAL	Income	53 681.00 EUR
	Expenditures	55 942.85 EUR

BALANCE - 2 261.85 EUR*

(*)Negative balance was due to 19 persons from 14 different developing countries who registered during the last month before the meeting and did not attend the meeting without payment and without cancellation. For these 19 registries, we had to pay a total of 3078 EUR (162 EURO per person) for services that could not be cancelled in due time (coffee breaks, lunches, dinner, farewell party, printed material)